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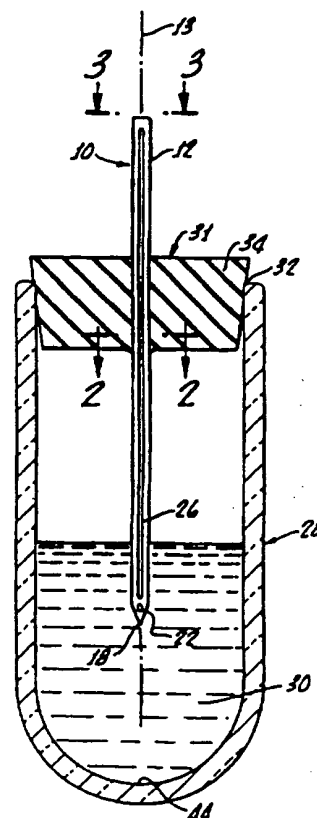
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : G01N 35/10		A1	(11) International Publication Number: WO 97/14967
			(43) International Publication Date: 24 April 1997 (24.04.97)
(21) International Application Number: PCT/US96/16642		(81) Designated States: AU, CA, JP, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).	
(22) International Filing Date: 18 October 1996 (18.10.96)			
(30) Priority Data: 08/545,978 20 October 1995 (20.10.95) US		Published With international search report.	
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(54) Title: VENTED PROBE AND METHOD FOR ADDING AND REMOVING A SAMPLE FROM A CONTAINER

(57) Abstract

A vented probe (10) for adding and removing a sample (30) from a container (28) having an opening (32) which is capped with a stopper (34) and a method for adding and/or removing a sample (30) from the container (28) are provided. The probe (10) comprises a hollow, tubular-shaped body (12) having an outer surface (14), an inner surface (16) which defines a lumen (17), and a first end (18) for inserting through the stopper (34) and a second end (20). A sample aperture (22) extends from the outer surface (14) into the lumen (17) proximate the first end (18) of the body (12) and a regulating aperture (24) extends through the body (12) into the lumen (17) proximate the second end (20) of the body (12). A vent passageway (26) is disposed in the body (12) between the first end (18) and the second end (20). The vent passageway (26) allows for venting of the container (28) when the probe (10) is disposed in the stopper (34). There is no direct communication between the vent passageway (26) and the lumen (17). The vent passageway (26) typically includes three spaced-apart grooves which extend longitudinally in the outer surface (14) of the body (12). These grooves each have a sufficient depth and width so that each groove is not occluded when the probe (10) is positioned in the stopper (34).



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VENTED PROBE AND METHOD
FOR ADDING AND REMOVING A SAMPLE FROM A CONTAINER

5

by

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10

BACKGROUND

This invention is directed to a system for adding and removing a sample from a closed container, such as a collection tube.

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A collection tube is commonly used to collection, store and preserve a sample such as a blood sample. The collection tube is typically a hollow cylindrical-shaped test tube having an opening which is capped with an elastomer stopper. The stopper seals the container to preserve the sample and prevent evaporation. The collection tube is commonly evacuated during the manufacturing process. Thus, the collection tube is subject to an initial vacuum which is intended to draw the sample into the tube.

25

Typically, the sample is initially transferred to the collection tube with a needle which is inserted through the stopper allowing the vacuum in the tube to draw the sample into the tube. After the sample is deposited in the collection tube, often a measured portion of the sample is removed by a probe for testing and experiments. Until recently, normal practice has been to remove the stopper from the collection tube in

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order to gain access to the sample. However, this procedure is not recommended since the sample in the collection tube is subject to contamination and evaporation and the people near the collection tube may
5 be exposed to diseases such as Hepatitis B and HIV from the sample.

Removal of the measured portion of the sample from the collection tube with the stopper in place
10 presents other difficulties. Once the probe is inserted through the stopper, the rubber typically seals around the probe. When a vacuum is created in a lumen of the probe to aspirate the measured portion of the sample, vacuum is created in the collection tube, in addition to
15 any residual vacuum which remains in the collection tube after the sample is drawn. Further, the withdrawal of the probe from the collection tube also increases vacuum in the collection tube.

20 The vacuum in the sealed collection tube causes aspiration of some of the sample from the lumen of the probe back into the collection tube. This adversely affects sample transfer precision since some of the measured portion of the sample is pulled back into the
25 collection tube. Further, transferring some of the sample from the lumen can pull contaminants from the lumen of the probe into the collection tube, thereby contaminating the sample remaining in the collection tube.

30 One attempt to solve this problem involves inserting a large cannula through the stopper and then inserting a probe through the lumen of the large cannula. The lumen of the large cannula has a larger diameter than

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the outer diameter of the probe so that venting of the collection tube occurs when the probe is disposed in the lumen of the large cannula.

5 However, this procedure has proved not to be entirely satisfactory since the large cannula remains in the stopper and keeps the collection tube vented even after the probe is removed. Thus, the sample remaining in the collection tube is subject to contamination and
10 evaporation and those near the collection tube may be exposed to a biohazard such as Hepatitis B and HIV. Further, an additional step is required to wash the large cannula and an additional step is required to insert the large cannula. Another approach is to use a disposable
15 cannula which does not require a washing step. The -disadvantage to this approach is the cost of the disposable cannulae plus the mechanism to insert them.

 Accordingly, there is a need for a probe which
20 can be used to precisely and easily add or remove a sample from a container, such as a collection tube without causing contamination to the sample, without any additional devices which need washing, without any additional devices which must be inserted into the
25 stopper and/or without the need to reseal the container. Additionally, there is a need for a method for precisely and easily adding and/or removing a sample from the container.

30 SUMMARY

 The present invention is directed to a vented probe and method that meet these needs, the vented probe and method being useful for adding and removing a sample

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from a container, i.e., a collection tube, having a pierceable area, i.e., a stopper. A vented probe according to the present invention comprises a hollow, tubular-shaped body having (i) an outer surface, (ii) an inner surface which defines a lumen, (iii) a first end for insertion through the stopper, (iv) a sample aperture extending into the lumen through the body, (v) a regulating aperture extending through the body into the lumen, proximate an opposed second end of the body and (vi) a vent passageway. The vent passageway is disposed in the body between the first and second ends. The vent passageway allows for venting of the container during addition and removal of a sample to and from the container with the probe extending through the stopper. There is no direct communication between the vent passageway and the lumen.

As used in this Application, no direct communication between the vent passageway and the lumen means that no gas, fluids or solids can flow directly between the vent passageway and the lumen. Gas, fluids or solids can transfer between the vent passageway and the lumen via the sample aperture or the regulating aperture.

As described in detail below, since the vent passageway allows the container to vent, the vacuum created in the container when a sample is removed or the pressure building-up in the container when a sample is added to the container is released. Thus, sample transfer precision is enhanced and there is less chance of contaminating the sample remaining in the collection tube. Further, since the vent passageway is disposed in the body of the probe, there is no additional device

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which requires washing, no additional device which must be inserted into the stopper to vent the container, and the stopper reseals after the probe has been removed to prevent evaporation and/or contamination of the sample
5 remaining in the collection tube.

The vent passageway can be a groove, and more preferably three spaced apart grooves to provide sufficient venting for the container. Each groove
10 extends longitudinally in the outer surface of the body and has a sufficient depth and width so that the vent passageway is not occluded when the probe is disposed in the stopper. Additionally, each groove is sufficiently
15 long so that the container is vented into the atmosphere when the probe is inserted in the stopper. For example, if the stopper has a thickness of "T", each groove extends longitudinally in the outer surface of the body a distance which is greater than "T".

The invention also includes a method for adding and removing a sample from a container. The method for removing a sample from the container includes the steps of (i) inserting a first end of a probe through the stopper until a sample aperture of the probe is disposed
25 in the sample, the sample aperture being in fluid communication with a lumen which extends longitudinally in the probe; (ii) creating a sufficient vacuum in the lumen to pull the sample into the lumen from the container through the sample aperture; and (iii) venting
30 the container through a vent passageway disposed in the probe. The vent passageway allows for the venting of the container without direct communication between the vent passageway and the lumen.

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The method for adding a sample to the container includes the steps of (i) inserting a first end of a probe through the stopper until a sample aperture of the probe is located inside the container, the sample
5 aperture being in fluid communication with a lumen containing a sample; (ii) pressurizing the lumen sufficiently to force a portion of the sample from the lumen into the container through the sample aperture; and
10 (iii) venting the container through a vent passageway disposed in the probe. The vent passageway allows for venting of the container without direct communication between the vent passageway and the lumen.

The present invention provides a vented probe
15 and a method for precisely adding and removing a sample from a container. Since the probe vents the container, sample transfer precision is greatly enhanced and there is less chance of contaminating the sample remaining in the container.

20

DRAWINGS

These and other features, aspects and
advantages of the present invention will become better
25 understood from the following description, appended claims and accompanying drawings where:

Figure 1 is a side, partial cut-away view of a
vented probe having features of the present invention
30 disposed in a container which is capped with a stopper;

Figure 2 is a cut-away view of a portion of the
vented probe and stopper of Figure 1 taken on line 2-2 in
Figure 1;

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Figure 3 is a top view of the vented probe of Figure 1 taken on line 3-3 in Figure 1;

Figure 4 is a cut-away view of a portion of the vented probe of Figure 1 taken on line 4-4 in Figure 1; and

Figure 5 is a side plan view of an analyzer with the vented probe of claim 1.

10

DESCRIPTION

A probe 10 according to the present invention comprises a hollow tubular-shaped body 12 having a longitudinal axis 13. The body 12 includes (i) an outer surface 14, (ii) an inner surface 16 which defines a lumen 17, (iii) a first end 18, (iv) a second end 20, (v) a sample aperture 22, (vi) a regulating aperture 24, and (vii) a vent passageway 26. Typically, the probe 10 is used with a syringe (not shown) or an analyzer 27 which creates a vacuum or pressure in the lumen 17 through the regulating aperture 24. An analyzer 27 suitable for use with the present invention is the SYNCHRON CX4 or SYNCHRON CX7 manufactured and sold by Beckman Instruments, Inc. of Fullerton, CA.

25

As shown in Figure 1, a container 28 is used to store a sample 30. Typically, the container 28 is a collection tube having a pierceable area 31. The pierceable area 31 is typically an opening 32 in the container 28 which is capped and sealed with a stopper 34. The stopper 34 is commonly made from an elastomer such as silicon rubber and typically is about one-quarter (1/4) inch thick. The probe 10 when used with the syringe is typically manually inserted into the

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stopper 34 and the analyzer 27 typically utilizes a crane 35 to insert and remove the probe 10 from the stopper 34.

5 The body 12 is typically formed from a length of hollow tubing which defines the outer surface 14 and the inner surface 16. The body 12 is terminated at the first end 18 in a conical-shaped pencil point tip which facilitates piercing of the stopper 34. Alternatively, the first end 18 could include a wedge-shaped tip. The
10 second end 20 is sized and shaped to be attached to the syringe or the analyzer 27 and is typically hollow tubular shaped.

The body 12 can be made from a number of
15 materials, including Inconel 625 or AISI type 304 stainless steel. The body 12 must be strong enough to not bend or deform during insertion into the stopper 34. For the type of materials detailed above, a wall 36 with a thickness of about fifteen thousandths (.015) of an
20 inch, an outer surface diameter of about ninety-three thousandths (0.093) of an inch and an inner surface diameter of about sixty-three thousandths (0.063) of an inch is typically sufficient.

25 The sample aperture 22 extends from the outer surface 14 into the lumen 17 proximate the first end 18. The sample aperture 22 is typically one or more holes which extend through the body 12 proximate the first end 18. The sample aperture 22 is sized (i) large enough to
30 not get plugged by the sample 30 or create a high back pressure in the lumen 17 and (ii) small enough to not weaken the probe 10 or get plugged by the stopper 34 during insertion through the stopper 34. Typically, a sample aperture 22 having a diameter of about thirty-

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thousandths (0.030) of an inch works sufficiently.

The regulating aperture 24 extends through the body 12 into the lumen 17, proximate the second end 20 of the body 12. Typically, the regulating aperture 24 is the opening at the second end 20 of the tubular body 12. Thus, the diameter of the regulating aperture 24 is typically the same as the diameter of the inner surface 16. The regulating aperture 24 is connected in fluid communication with a syringe or an analyzer 27 to add a sample 30 to the container 28 or remove the sample 30 from the container 28 with the probe 10.

The vent passageway 26 allows for venting of the container 28 when the probe 10 is disposed in the stopper 34. The vent passageway 26 is located between the first end 18 and the second end 20 of the body 12. The vent passageway 26 does not extend into the lumen 17 and there is no direct communication between the vent passageway 26 and the lumen 17. The vent passageway 26 can be a groove which extends longitudinally in the outer surface 14 of the body 12. Additional grooves in the outer surface 14 provide additional venting to the container 28. However, additional grooves also weaken the body 12. Three spaced apart grooves typically provide sufficient venting without unduly weakening the body 12.

The grooves are each sized and configured such that the stopper 34 does not occlude them when the probe 10 is disposed in the stopper 34. This is accomplished by having a sufficient shape, depth and width which is beyond the ability of the stopper 34 to conform. Accordingly, the shape, depth and width of the grooves

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vary according to the material used in the stopper 34. The shape, depth and width of the grooves also vary according to the material and wall 36 thickness of the body 12. As previously discussed, typically, the stopper 34 is made from an elastomer such as silicon rubber. As shown in Figure 4, each groove can have a right triangular, cross-sectional shape. Grooves having (i) a depth 38 of about between .003-.015 inches and preferably .010 inches when measured from a continuation of the arc 39 (shown in dashed lines in Figure 4) of the circular cross-sectional outer surface, and (ii) a width 40 at the outer surface 14 of about between .003-.030 inches and preferably .014 inches, provide sufficient venting ability so that the stopper 34 will not conform to and occlude the grooves. In the embodiments shown in the drawings, a bottom 42 of each groove is cut at approximately a 90° angle for ease of machining. Alternatively, each groove can be another shape, such as that of a rectangle or a half-circle.

20

Each groove can be machined, i.e., milled or electro discharge machined into the outer surface 14 of the probe 10.

25

Each vent passageway 26 is sufficiently long so that the container 28 is vented into the atmosphere when the probe 10 is inserted to the desired depth in the container 28 through the stopper 34. For example, if the stopper 34 has the thickness of "T", each vent passageway 26 extends longitudinally in the outer surface 14 of the body 12 a distance which is greater than "T". Typically, the stopper 34 has a thickness of about one quarter (1/4) of an inch. Accordingly, each vent passageway 26 is typically at least about one-quarter (1/4) of an inch or

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longer.

Preferably, each vent passageway 26 extends longitudinally substantially along the entire length of the body 12 so that the container 28 is vented regardless of the position of the probe 10 in the container 28. Thus, the container 28 is vented if a sample 30 is drawn from a bottom 44 of the container 28 and the container 28 is vented as the probe 10 is being removed from the container 28. Probes 10 are typically about eight (8) inches long. Accordingly, each vent passageway 26 can be between about one-quarter ($\frac{1}{4}$) to eight (8) inches long.

In operation, for the removal of a sample 30 from the container 28, the first end 18 of the probe 10 is inserted through the stopper 34 until the sample aperture 22 is positioned in the sample 30. A vacuum is created in the lumen 17 through the regulating aperture 24 by a source of vacuum 46 in the syringe or the analyzer 27. The vacuum causes the sample 30 to be aspirated from the container 28 into the lumen 17 through the sample aperture 22. During aspiration, the vent passageway 26 vents the container 28 from the atmosphere. After a portion of the sample 30 is moved into the lumen 17 and then into a barrel (not shown) of the syringe or analyzer 27, the probe 10 is removed. During removal of the probe 10, the vent passageway 26 vents the container 28, thereby reducing any possible vacuum created by the removal of the probe 10.

30

For the addition of a sample 30 to the container 28, the first end 18 of the probe 10 is inserted through the stopper 34 until the sample aperture 22 is positioned inside the container 28. Pressure is

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applied in the lumen 17 through the regulating aperture 24 by the syringe or the analyzer 27. The pressure causes the sample 30 to be pushed from the barrel of the syringe or analyzer 27 and the lumen 17
5 into the container 28 through the sample aperture 22. During this process, the container 28 is vented through the vent passageway 26.

The present invention provides a probe 10
10 having a vent passageway 26 which vents the container 28 during adding and/or removing of sample 30 from a container 28. Therefore, sample transfer precision is enhanced and the chances of contamination during adding and removing of the sample 30 from the container 28 is
15 reduced. The significant advantages of the present invention are that only the probe 10 is inserted through the stopper 34, only the probe 10 must be washed and the container 28 typically seals upon removal of the probe 10 from the stopper 34.

20

Although the present invention has been described in considerable detail with reference to certain preferred versions, other versions are possible. For example, the vent passageway 26 could be a
25 longitudinal apertures (not shown) which extends longitudinally in the wall 36 of the body 12 between the outer surface 14 and the inner surface 16 with a first transverse aperture (not shown) extending transversely into the body 12 from the outer surface 14 into the
30 longitudinal aperture proximate the first end 18 and a second transverse aperture (not shown) extending transversely into the body 12 from the outer surface 14 into the longitudinal aperture proximate the second end 20. However, this version would be more expensive to

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manufacture and more difficult to wash. Therefore, the spirit and scope of the appended claims should not be limited to descriptions of preferred versions contained herein.

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We claim:

1. A probe for adding and removing a sample from a container having a pierceable area, the probe
5 comprising, a hollow, tubular shaped body having: (i) an outer surface; (ii) an inner surface which defines a lumen; (iii) a first end suitable for insertion through the pierceable area and an opposed second end of the
10 body; (iv) a sample aperture extending from the outer surface into the lumen, proximate the first end; (v) a regulating aperture extending through the body into the lumen; and (vi) a vent passageway disposed in the body between the first and second ends which is not occluded
15 by the pierceable area and allows for venting of the container when the probe is disposed in the pierceable area:

wherein, there is no direct communication between the vent passageway and the lumen.

20 2. The probe of claim 1 wherein the vent passageway is a groove disposed in the outer surface of the body, the groove having sufficient depth and width so that the groove is not occluded when the probe is
25 disposed in the pierceable area.

3. The probe of claim 1 wherein the vent passageway is a groove extending longitudinally in the outer surface of the body.

30 4. The probe of claim 3 wherein the groove has a depth of at least about .003 inches.

5. A system for adding and removing a sample from storage, the system comprising: (i) a container

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having an opening which is sealed with a stopper, the stopper having a thickness of "T" and (ii) the probe of claim 1 disposed in the stopper, wherein the vent passageway extends longitudinally in the body a distance
5 which is greater than "T".

6. The probe of claim 1 wherein the vent passageway extends longitudinally in the body at least about 0.25 inches.
10

7. The probe of claim 1 wherein the body includes at least two vent passageways disposed in the body between the first and second ends which allow for the venting of the container during adding and removing
15 of a sample from the container with the probe.

8. The probe of claim 1 wherein the vent passageway comprises three spaced-apart grooves which extend longitudinally in the outer surface of the body,
20 each groove having sufficient depth and width so that each groove is not occluded when the probe is disposed in the pierceable area.

9. An analyzer for removing a sample from a collection tube having an opening which is capped with a stopper, the analyzer comprising:
25

- (i) the probe of claim 1;
- (ii) a crane for pushing the probe through the stopper; and
- 30 (iii) a source of vacuum in communication with the regulating aperture for creating a vacuum in the lumen and drawing a portion of the sample into the lumen.

10. A method for withdrawing a sample from a

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container having an opening which is capped with a stopper, the method comprising the steps of:

- (i) inserting the first end of the probe of claim 1 through the stopper until the sample aperture of the probe is located in the sample, the sample;
- (ii) creating a vacuum in the lumen sufficient to pull a portion of the sample into the lumen from the container through the sample aperture; and
- (iii) venting the container through a vent passageway disposed in the probe, the vent passageway allowing for the venting of the container without direct communication between the vent passageway and the lumen.

15

11. A method for adding a sample to a container having an opening which is capped with a stopper, the method comprising the steps of:

- (i) inserting the first end of the probe of claim 1 through the stopper until the sample aperture of the probe is located inside the container, wherein the lumen contains a sample;
- (ii) pressurizing the lumen sufficiently to force a portion of the sample from the lumen into the container through the sample aperture; and
- (iii) venting the container through the vent passageway disposed in the probe.

30

12. A probe for adding and removing a sample from a container having an opening which is sealed with a stopper, the probe comprising, a hollow, tubular shaped body having: (i) an outer surface; (ii) an inner surface which defines a lumen; (iii) a first end suitable for

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insertion through the rubber stopper; (iv) a first aperture extending from the outer surface into the lumen, proximate the first end; (v) a second aperture extending through the body into the lumen, proximate a second end of the body; and (vi) three spaced-apart grooves disposed in the outer surface of the body between the first and second ends which allow for the venting of the container during adding and removing of a sample from the container with the probe, each groove having a sufficient depth and width so that each groove is not occluded when the probe is disposed in the stopper;

wherein, there is no direct communication between the grooves and the lumen.

13. The probe of claim 12 wherein each groove extends longitudinally in the outer surface of the body.

14. A system for adding and removing a sample, the system comprising: (i) a container having an opening which is sealed with a stopper, the stopper having a thickness of "T" and (ii) the probe of claim 12 disposed in the stopper, wherein the vent passageway extends longitudinally in the body a distance which is greater than "T".

15. The probe of claim 12 wherein the vent passageway extends longitudinally in the body at least about 0.25 inches.

16. An analyzer for removing a sample from a collection tube having an opening which is capped with a stopper, the analyzer comprising:

- (i) the probe of claim 12;
- (ii) a crane for pushing the probe

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through the stopper; and

(iii) a source of vacuum in communication with the regulating aperture for creating a vacuum in the lumen and drawing a portion of the sample into the lumen.

5

17. A method for withdrawing a sample from a container having an opening which is capped with a stopper, the method comprising the steps of:

(i) inserting a first end of a probe
10 through the stopper until a sample aperture of the probe is located in the sample, the sample aperture being in fluid communication with a lumen which extends longitudinally in the probe;

(ii) creating a vacuum in the lumen
15 sufficient to pull a portion of the sample into the lumen from the container through the sample aperture; and

(iii) venting the container through a vent passageway disposed in the probe, the vent passageway allowing for the venting of the container
20 without direct communication between the vent passageway and the lumen.

18. The method of claim 17 wherein the step of venting the container comprises the step of venting the
25 container through a groove in an outer surface of the probe.

19. The method of claim 17 wherein the step of venting the container comprises the step of venting the
30 container through three, spaced-apart grooves which extend longitudinally in an outer surface of the probe.

20. A method for adding a sample to a container having an opening which is capped with a

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stopper, the method comprising the steps of:

(i) inserting a first end of a probe through the stopper until a sample aperture of the probe is located inside the container, the sample aperture being in fluid communication with a lumen disposed in the probe, the lumen containing a sample;

(ii) pressurizing the lumen sufficiently to force a portion of the sample from the lumen into the container through the sample aperture; and

(iii) venting the container through a vent passageway disposed in the probe, the vent passageway allowing for the venting of the container without direct communication between the vent passageway and the lumen.

21. The method of claim 20 wherein the step of venting the container comprises the step of venting the container through a groove in an outer surface of the body.

22. The method of claim 20 wherein the step of venting the container comprises the step of venting the container through three, spaced-apart grooves which extend longitudinally in an outer surface of the probe.

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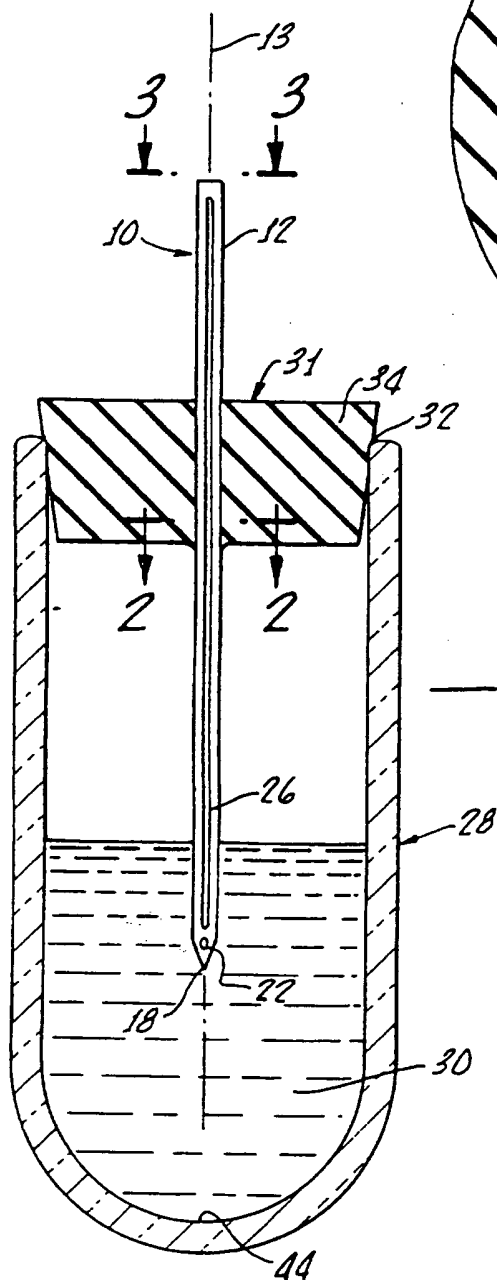


FIG. 1.

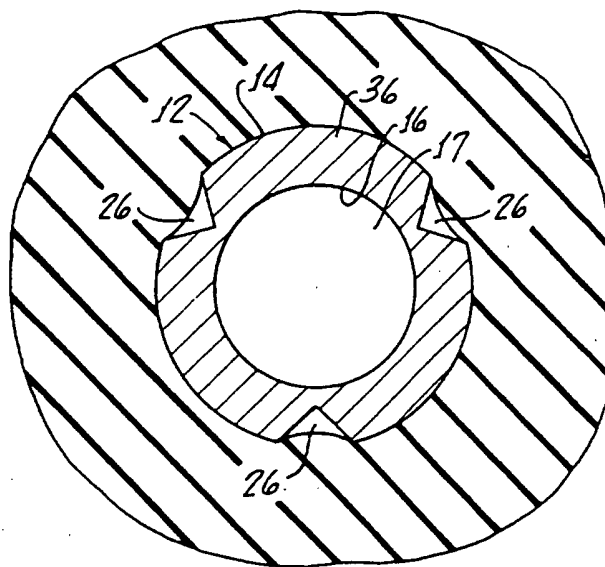


FIG. 2.

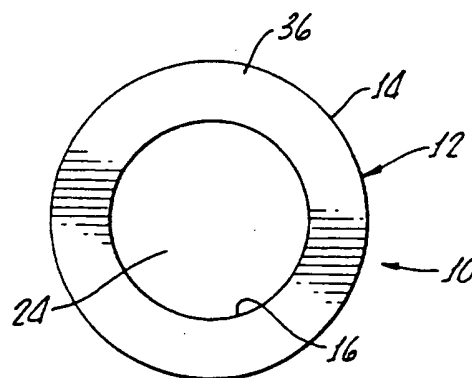


FIG. 3.

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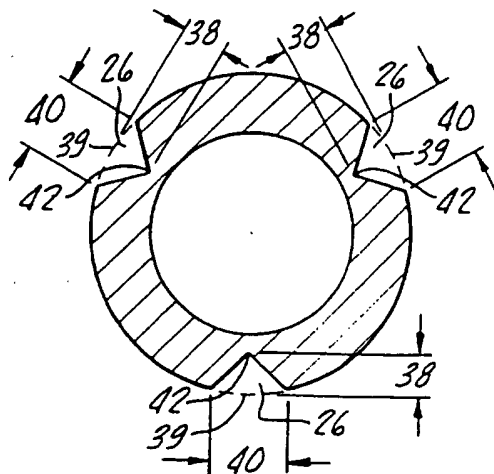


FIG. 4.

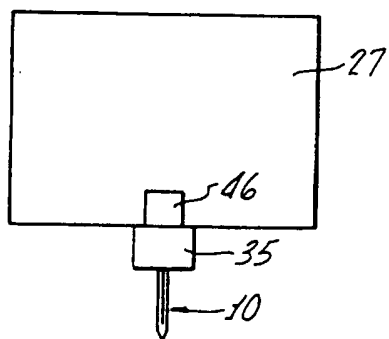


FIG. 5.

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 96/16642

A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 G01N35/10

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 G01N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 95 06867 A (AUTOMED CORP) 9 March 1995	1-3,5,7, 9-11,17, 18,20,21
Y	see page 10, line 17 - page 22, line 29	12-14, 16,19
X	US 3 063 451 A (KOWALK ARTHUR J) 13 November 1962	1-3,5,7, 8,20-22
Y	see the whole document	12-14, 16,19
X	US 5 431 067 A (ANDERSON JOHN D ET AL) 11 July 1995	1,5,10, 11,20
A	see column 14, line 20 - column 15, line 58; figures 9-15	9,16
	-/--	

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

30 January 1997

Date of mailing of the international search report

-7. 02. 97

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 96/16642

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